

**REMARKS**

Reconsideration and allowance of the subject patent application are respectfully requested.

Claim 8 and 9 have been amended to rewrite "pda" as "PDA" and withdrawal of the objections to these claims is respectfully requested.

Claims 1-6, 8-11, 13, 15, 18-24, 28-30, 36 and 37 were rejected under 35 U.S.C. Section 102(b) as allegedly being "anticipated" by Schulze et al. (U.S. Patent Publication No. 2002/0019584). While not acquiescing in this rejection or in the characterizations of Schultze et al. made in the office action, claim 1 has been amended to even more clearly distinguish over Schultze et al.

For example, claim 1 now recites that the operation of the measurement of the patient's condition is "under the control of the patient." Claim 1 further recites that the server includes an automatic message generator which generates and sends to the patient messages which are automatically adapted in response to the automated trend analysis.

Among other things, Schulze et al. does not disclose any automatic adaptation of messages or automatic selection of questions in response to the measurement, nor does Schulze et al. disclose any automated trend analysis with respect to trends which are tuned to a patient's characteristics as set forth in claim 1.

More specifically, paragraph [0153] of Schulze et al. discloses the storing of questions "in a messaging profile" but this paragraph goes on to indicate that "[a] 'Care Manager' picks from pre-selected messages to be sent at a pre-selected time of day."

It is therefore clear that the questions are under the control of the care manager and are not "changed by automatic download controlled by the server in response to changes in the patient's condition as measured by the electronic physiological data acquisition unit" as specifically recited in claim 1.

As regards the analysis of trends, Schulze et al. discloses that the data is analyzed for trends that can be used for alarm setting (see paragraph [0062]). However, Schulze et al. does not disclose that this analysis is conducted automatically by a trend analyzer in the server. Instead paragraph [0033] makes it clear that the alarms are "set remotely by the healthcare provider over the internet." It is a key point of Schulze et al. that it is the care giver who is

responsible for interpreting the limits for the patient. This is further emphasized in paragraph [0125] which states that “[l]imits for each patient will be different, and must be interpreted by a care giver.”

Further, paragraph [0115] discloses that “[b]oth the limits and the persistent period for each parameter are set by the care giver.”

Thus, this contrasts with the system of claim 1 in which trend analysis is performed with respect to a tuned trend, and adaptation of questions for display to the patient are automatic. The patient does not have to wait for a doctor to interpret the measurement and send a response, and the burden on the caregiver is correspondingly reduced.

Claim 1 as amended therefore recites several features which are not present in Schulze et al. and thus claim 1 and its dependent claims cannot be anticipated by Schulze et al.

Claims 36 and 37 have been amended along the same lines as claim 1 and these claims are likewise not anticipated by Schulze et al.

Claims 1-5, 8-11, 13-16, 18-30, 36 and 37 were rejected under 35 U.S.C. Section 103 as allegedly being made “obvious” by Walker et al. (U.S. Patent No. 6,302,844) in view of Schulze et al.

In relation to claim 1, Walker et al. lacks the feature that in response to an automated trend analysis conducted in the server, the server automatically adapts questions that extend to the patient-based device. The only querying of the patient disclosed in Walker et al. is in column 8, lines 18 to 39, but this section makes it clear that the server reaction is based on the alert code supplied by the patient-based device. Thus according to Walker et al. it is the local patient-based device which has to obtain an alert code, this alert code is sent to the server and in response to this alert code the table 305 is used to generate a response.

It is also important to understand that an alert is a response to a data value exceeding a limit. A “limit” is not a “trend.” A trend can be viewed as a recognizable temporal pattern in a time series of data points. A limit is simply an artificial value to which a data point is compared, but the limit is not a data point itself.

Thus with Walker et al. (and with Schulze et al. also), the response sent to the patient tends to be in the form of an alarm that the patient's condition is anomalous. This is, of course, alarming to the patient. A significant advantage of the claim 1 system is that the message

relating to the patient's condition and which gives useful feedback is always sent in order that the patient can enjoy quantitative feedback which may be positive.

The reason this is important is that it has been found that with chronic medical conditions, a patient can be motivated to take control of his or her health by monitoring it reliably and carefully and following the feedback. Then, over time, the better control of the condition can actually improve the health of the patient. However, one does not want to over-burden clinicians, and so a further significant advantage of the claim 1 system is that the patient is provided with message-based feedback which is tuned to their own characteristics, but which is generated automatically. Thus, as recited in claim 1, the tuned trend analysis is automatic, as is the adaptive message generation. A clinician does not have to be involved.

The philosophy of Walker et al. and Schulze et al. (and in fact the philosophy of the prior art in general) is that the patient is normally given very limited feedback, but is given alarms if their condition becomes abnormal. Further, in many prior art systems the operation is not under the control of the patient, but is under the control of the central server, which renders the patient passive. Such systems tend to disempower and demotivate patients and thus in practice have not been successful. For example, the system of Schulze et al. is a patient-wearable monitoring unit which provides continuous and passive monitoring of the patient's condition. It is not like the claim 1 system which requires the patient to initiate the measurement, and then automatically gives adaptive feedback on that measurement.

Thus the aim with the claim 1 system is to have an active and involved patient, but not to burden the clinician. This has been found to enhance the attractiveness of the system both to patients and clinicians.

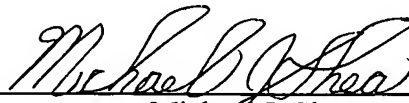
Applicant respectfully submits that the claim 1 system provides significant advantages in practice over the prior art and thus is not obvious from the prior art.

Claims 36 and 37 are believed to patentably distinguish from the proposed Walker et al. - Schulze et al. combination for reasons similar to those discussed above with respect to claim 1.

Applicant believes that this entire application is in condition for allowance and respectfully requests a notice to this effect. If the Examiner has any questions or believes that an interview would further prosecution of this application, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By:   
Michael J. Shea  
Reg. No. 34,725

MJS:mjs  
901 North Glebe Road, 11th Floor  
Arlington, VA 22203-1808  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100